# Focus Report

New Chemicals Program

PMN Number: **L-14-0271**

| | | | |
|---|---|---|---|
| Focus Date: | 04/30/2014 11:00:00 PM | Report Status: | Completed |
| Consolidated Set: | | | |
| Focus Chair: | Jeff Bauer | Contractor: | Olga Svetlitskaya |

## I. Notice Information

| | | | |
|---|---|---|---|
| Submitter: | Resman USA | CAS Number: | [redacted] |
| Use: | Tracer for production monitoring in oil and gas wells. [redacted] P2REC: CRSS: forward. P2 Claims: The LVE substance can replace radioactive, high volume chemical, or fluorinated tracers. | | |
| Other Uses: | [redacted] . | | |
| PV-Max: | 10,000 Kg/yr | Binding Option: | No |
| Manufacture: | | Import: | X |

## II. SAT Results

(1) **Health Rating:** 1-2 **Eco Rating:** 3 **Comments:** ;

**Occupational:** 1C **Non-Occupational:** 1 **Environmental:** 1

(1) **PBT:** 3 1 1 **Comments:**

Awaiting Human Health Entry

Awaiting Human Health Entry

Awaiting Human Health Entry

## III. OTHER FACTORS

**Categories:**

| | | | |
|---|---|---|---|
| Health Chemical Category: | | Ecotox SAR and TSCA New Chemical Category: | Neutral Organics; Neutral Organics |

**Related Cases/Regulatory History:**

| | |
|---|---|
| Health related Cases: | [redacted] |
| Ecotox Related Cases: | Analogs: [redacted] |
| Regulatory History: | [redacted] - GRANTED WITH CONDITION (FCG) |
| CRSS P2Rec: | P2Rec-P2 Recognition |

**MSDS/Label Information:**

| | | | |
|---|---|---|---|
| MSDS: | Yes | Label: | No |
| General Equipment: | gloves (selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it) / Safety glasses with side-shields conforming to EN166. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN166 (EU). / Impervious clothing (e.g. work overall, apron, lab coat). | | |
| Respirator: | For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator. For higher level protection use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU). | | |
| Health Effects: | Inhalation of dust from the break down products may cause headaches or respiratory irritation. Prolonged or repeated exposure can irritate eyes and skin. | | |

TLV/PEL (PMN or raw material): - none established.
LVEPPE: Solid form, PPE: gloves, eye protection

**Exposure Based Information:**

Exposure Based Review: N
Exposure Based Review (Eco): N
Exposure Based Review (Non Occupatuional):
Exposure Based Review (Health): N
Exposure Based (Occupational): No
Exposure Based (Environmental):

## IV. Summary of SAT Assessment

### Fate:

**Fate Summary:**

L-14-0271
FATE: [redacted]
Liquid with MP < 25 C (E)
S = 39 mg/L at 25 °C (E)
VP < 1.0E-6 torr at 25 C (E)
BP > 400 C (E)
H < 1.00E-8 (E)
POTW removal (%) = 0-25 via sorption and biodeg; OECD 306(Closed Btl, Seawater): 0%/28d.
Time for complete ultimate aerobic biodeg ≥ mo
Sorption to soils/sediments = moderate
PBT Potential: P3B1
*CEB FATE: Migration to ground water = moderate

### Health:

**Health Summary:** Poor absorption all routes based on physical/chemical properties. There are uncertain concerns for solvent irritation to the eye, lung, and mucous membranes.

### Ecotox:

**Ecotox Values:**

| | | |
|---|---|---|
| Fish 96-h LC50: | 21.7(P) | |
| Daphnid 48-h LC50: | 14.2(P) | 1.6(M) |
| Green algal 96-h EC50: | 19.1(P) | 0.06(M) |
| Fish Chronic Value: | 2.5(P) | |
| Daphnid ChV: | 2.1(P) | |
| Algal ChV: | 6.9(P) | 0.032(M) |

**Ecotox values comments:** Predictions are based on SARs for neutral organics; SAR chemical class = neutral organics; MW [redacted] log Kow = 3.2 (EPI[redacted]; liquid with unknown mp (P); S = 32 mg/L at 20 C, pH 7 (P); pH7; effective concentrations based on 100% active ingredients and nominal concentrations; DW hardness <150.0 mg/L as CaCO3; and DW TOC <2.0 mg/L;

Ecotoxicity Test Data Results for L-14-0271: [redacted]

Data submitted with L-14-0271 [redacted] rade Name: RGTO-015) were for saltwater species that included the marine invertebrates Acartia tonsa and Mysidia bahia, the sediment dwelling invertebrate Corophium volutater, the marine diatom Skeletonema costatum, and the marine fish Menidia beryllina (Inland silverside). The PMN substance was classified as a Neutral Organics with a moderate predicted water solubility (39 mg/L). Predictions for fate and effects were carried out with a representative structure that contained [redacted]. The molecular weight was [redacted]

Fish Ecotoxicity Test:
Environmental Enterprises USA, Inc. conducted a 7-day toxicity study in the inland silverside

(Menidia beryllina) with L-14-0271 (purity not specified) under static-renewal conditions with daily renewal. This study was reported to follow the requirements of EPA-821-R-02-014: "Short Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Marine and Estuarine Organisms" with strict adherence to the requirements of Method 1006. Five replicates of eight M. beryllina were exposed to a dilution water control (synthetic seawater) or the test substance as water accommodated fractions (WAFs) at nominal concentrations of 0.1, 0.5, 2.5, 12.5 and 62.6 parts per trillion (ppt). A 500,000 ppb WAF stock solution was prepared by adding 0.5 g of test substance to 1000 mL of diluent in a 1-L aspirator bottle. The WAF was then mixed for 24 hours on a magnetic stirrer using ½" diameter by 3" long stir bars. The depth of the vortex of each was adjusted to approximately 1/3 the total depth of the solution. After mixing for 24 hours, the WAF was allowed to settle for 60 minutes. After settling, the WAF was collected from the tubular outlet of the aspirator bottle. A second stock solution (5,000,000 ppt) was prepared and used to make a third stock solution at 5,000 ppt. This third stock solution was used to prepare the initial and subsequent renewal test solutions. During the study, temperature was maintained at 25 ± 1°C. The salinity of the dilution water (synthetic seawater) was 25 parts per thousand. There were no significant effects on survival or growth. Based on nominal concentrations, the 7-day NOEC and LOEC values were 62.6 and > 62.6 ppt, respectively, for both survival and growth. This study was considered unacceptable to characterize the chronic fish endpoint since the highest test concentration was greatly below the limit of solubility and 10 mg/L and did not result in an effects determination. In addition the duration was too short.
7-day NOEC (survival and growth) = 62.6 ppt (0.0000626 mg/L)
7-day LOEC (survival and growth) > 62.6 ppt (0.0000626 mg/L)

Invertebrate Ecotoxicity Test:
(1) Opus Plus Limited conducted a 10-day sediment bioassay in marine amphipods (Corophium volutator) with L-14-0271 (purity not specified). Test methods were conducted in accordance with SOP 102, which conforms to the Paris Commission guidelines for conducting sediment toxicity tests with the amphipod Corophium volutator (OSPARCOM 2006). Three replicates of twenty C. volutator were exposed to the test substance at nominal wet weight concentrations of 10, 100, 320, 1000 and 10000 mg/kg. Corresponding nominal dry weight concentrations of 16.34, 161.13, 509.84, 1573.66 and 14690.82 mg/kg were calculated using a wet-to-dry sediment ratio of 1.62. Additionally, five control replicates were tested concurrently in amended sediment combined with filtered seawater. The test substance was considered to be poorly soluble in a preliminary test and was therefore added to the test system via dried sediment. Tests were conducted in 1 L capacity glass beakers each containing 2 cm depth (approximately 150 mL) of amended sediment and 850 mL of overlying seawater (1 ìm filtered ultra violet treated seawater). To prepare the test medium, an appropriate amount of test substance was initially mixed with a small quantity of dry sediment. The dried sediment and mixed test material was then incorporated with the wet sediment within the mixing container. The mixing vessels were then placed on a platform shaker at approximately 150 rpm for 3 hours. After this period, the contents of each container were equally distributed between the replicate vessels. Vessels were covered with a sheet of Perspex perforated with a small hole above the center of each beaker. Aeration was provided and a stream of air bubbles was released at a depth of approximately 6 cm. Over the course of the study, temperature ranged from 14.4-15.5°C, pH ranged from 7.78-8.21, dissolved oxygen ranged from 79-96% and salinity ranged from 35-40 ppt. Mean percent mortality at 0 (control), 16.34, 161.13, 509.84, 1573.66 and 14690.82 mg/kg was 2%, 6.7%, 3.3%, 100%, 100% and 100%, respectively. Based on nominal concentrations, the 10-day LC50 was 330 mg/kg (dry weight). The NOEC and LOEC values were 161 and 510 mg/kg (dry weight), respectively. The 10-day ChV was 286.5 mg/kg (dry weight). Although the approach is reasonable, the organic carbon content of the sediment was not clearly provided and since organic carbon content of sediment may impact the results of the study, there are uncertainties with the results. In addition, a table of the results should have been provided.

10-day LC50 = 330 mg/kg (dry weight)
10-day NOEC = 161 mg/kg (dry weight)
10-day LOEC = 510 mg/kg (dry weight)
10-day ChV = 286.5 mg/kg (dry weight)

(2) Opus Plus Limited conducted a 48-hour toxicity study in marine copepods (Acartia tonsa) with L-14-0271 (purity not specified). This study was reported to follow ISO guideline No. 14669 (1999), Water Quality – Determination of acute lethal toxicity to marine copepods and ISO guideline No. 5667-16 (1998), Water Quality Sampling – Guidance on biotesting of samples. The

test substance was considered to be poorly soluble in a preliminary test; therefore, exposures were carried out with water accommodated fractions (WAFs). Following a range-finding study, two replicates of ten A. tonsa were exposed to test substance WAFs at nominal concentrations of 0.1, 0.32, 1.0, 3.2 and 10.0 mg/L. Additionally, four replicates of ten A. tonsa were exposed to a dilution water control (treated seawater). WAFs were prepared by the direct addition of the required amount of test substance to seawater followed by gentle stirring for approximately 20 hours and a settling period of approximately one hour. After this settling period, the middle phase of the preparation was siphoned, avoiding incorporation of undissolved particles, if present. During the study, temperature ranged from 19.3-20.9°C and dissolved oxygen ranged from 86-88%. At the start of the study, the pH ranged from 8.09-8.22. The salinity of the dilution water was 36‰. A loading rate of 200 copepods/L was calculated. Mean percent mortality at 0 (control), 0.1, 0.32, 1.0, 3.2 and 10.0 mg/L was 2.5%, 9.6%, 25%, 33.2%, 100% and 100%, respectively. Based on nominal concentrations, the 48-hour LC50 was 1.59 mg/L. Based on the use of WAF methodology and the absence of analytic confirmation of test concentrations, observed adverse effects may have occurred at concentrations of less than the nominal values reported. Other concerns with the study include no reporting of test substance composition in the study report; however, a PMN attachment does provide more polymer weight information for RGTO-015. Considering that the study followed an established guideline and considering that effects were observed at concentrations less than the water solubility limit, the study was considered acceptable.
48-hour LC50 = 1.59 mg/L

(3) Environmental Enterprises USA, Inc. conducted a 7-day survival, growth and fecundity test in mysids (Mysidopsis bahia) with L-14-0271 (purity not specified) under static-renewal conditions with daily renewal. This study was reported to follow the requirements of EPA-821-R-02-014: "Short Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Marine and Estuarine Organisms" with strict adherence to the requirements of Method 1007 and/or the Western Gulf of Mexico OCS General Permit. Eight replicates of five M. bahia were exposed to a dilution water control (synthetic seawater) or the test substance as water accommodated fractions (WAFs) at nominal concentrations of 0.1, 0.5, 2.5, 12.5 and 62.6 parts per trillion (ppt). A 500,000 ppb WAF stock solution was prepared by adding 0.5 g of test substance to 1000 mL of diluent in a 1-L aspirator bottle. The WAF was then mixed for 24 hours on a magnetic stirrer using ½" diameter by 3" long stir bars. The depth of the vortex of each was adjusted to approximately 1/3 the total depth of the solution. After mixing for 24 hours, the WAF was allowed to settle for 60 minutes. After settling, the WAF was collected from the tubular outlet of the aspirator bottle. A second stock solution (5,000,000 ppt) was prepared and used to make a third stock solution at 5,000 ppt. This third stock solution was used to prepare the initial and subsequent renewal test solutions. During the study, temperature was maintained at 26 ± 1°C. The salinity of the dilution water (synthetic seawater) was 25 parts per thousand. A loading rate of 33 M. bahia/L was calculated. There were no significant effects on survival or growth. Based on nominal concentrations, the 7-day NOEC and LOEC values were 62.6 and > 62.6 ppt, respectively, for both survival and growth. This study was considered unacceptable to characterize the chronic invertebrate endpoint since the highest test concentration was greatly below the limit of solubility and 10 mg/L and did not result in an effects determination. In addition the duration was too short.
7-day NOEC (survival and growth) = 62.6 ppt
7-day LOEC (survival and growth) > 62.6 ppt

Algal Ecotoxicity Test:
Opus conducted a 72-hour toxicity study in marine algae (Skeletonema costatum) with L-14-0271 (purity not specified) under static conditions. This study was reported to follow SOP 104, ISO guideline No. 10253 (2006), Water quality – Marine algal growth inhibition test. The test substance was considered to be poorly soluble in a preliminary test; therefore, exposures were carried out with water accommodated fractions (WAFs). Following a range-finding study, three replicates of S. costatum (10,000 cells/mL) were exposed to test substance WAFs at nominal concentrations of 0.1, 0.032, 0.1, 0.32 and 1.0 mg/L. Additionally, six replicates of S. costatum (10,000 cells/mL) were exposed to a dilution control (treated seawater with nutrient medium). The algae were illuminated with a light intensity ranging from 6120-7750 lux with constant shaking. WAFs were prepared by the direct addition of the required amount of test substance to seawater followed by gentle stirring for approximately 20 hours and a settling period of approximately one hour. After this settling period, the middle phase of the preparation was siphoned, avoiding

incorporation of undissolved particles, if present. During the study, temperature ranged from 20.7-21.7°C and pH ranged from 8.01-8.67. Salinity of the dilution medium was 36‰. Based on nominal concentrations, the 72-hour EC50 for growth rate was 0.06 mg/L. The 72-hour NOEC and LOEC values were 0.032 and 0.1 mg/L, respectively; since the LOEC is greater than the EC50 a ChV is not calculated. Based on the use of WAF methodology and the absence of analytic confirmation of test concentrations, observed adverse effects may have occurred at concentrations of less than the nominal values reported. Other concerns with the study include no reporting of test substance composition in the study report; however, a PMN attachment does provide more polymer weight information for RGTO-015. Considering that the study followed an established guideline and considering that effects were observed at concentrations less than the water solubility limit, the study was considered acceptable.
72-hour EC50 = 0.06 mg/L
72-hour NOEC = 0.032 mg/L
72-hour LOEC = 0.1 mg/L

Both acute and chronic duration studies were provided; however, those chronic studies did not test to a high enough concentration to result in an effects determination and did not test to a sufficient duration. Even though concerns with study methodology were reported for the acute studies, submitted acute studies were guideline and suggested hazard in saltwater environments specific for this PMN. Predictive techniques were used to assess chronic hazard levels. An acute CoC of 0.015 mg/L (15 ppb) was calculated from the marine algae 72-hour EC50 of 0.06 mg/L with application of an assessment factor of 4 to account for species sensitivity distributions. A chronic CoC of 3 ppb was calculated from the marine algae NOEC of 0.032 (NOEC used since the LOEC>EC50) and an assessment factor of 10.

Acute CoC: 0.015 mg/L (15 ppb)
Chronic CoC: 0.003 mg/L (3 ppb)

Reviewer: K.Moran

**Ecotox Factors:**

| | |
|---|---|
| Assessment Factor: | 10 |
| Concern Concentration: - Acute Value | |
| Concern Concentration: - Chronic Value | 3 |

## V. Summary of Exposures/Releases

Engineering Summary: L-14-0271

| Exposures/Releases | Release | Release | Release |
|---|---|---|---|
| **Scenario** | **Use: Tracer Chemical in Oil and Gas Wells** | **Use: Tracer Chemical in Oil and Gas Wells** | **Use: Tracer Chemical in Oil and Gas Wells** |
| **Sites** | **124** | **124** | **124** |
| **Media** | **Incineration** | **Water** | **Water or Landfill** |
| Descriptor A | Output 2 | Output 2 | Output 2 |
| Quantity A (kg/site/day) | 2.3E-1 | 5.9E-5 | 1.0E-4 |
| Frequency A (day/year) | 350 | 350 | 350 |
| Descriptor B | | | |
| Quantity B (kg/site/day) | | | |
| Frequency B (day/year) | | | |
| From | Release to Refinery from Separation Process | Release to Water from Off-Shore Separation Process | Equipment and Storage Tank Cleaning |
| Workers | | | |
| Exposure Type | | | |

| Engineering Summary: Exposures/Releases | Exposure | | |
|---|---|---|---|
| **Scenario** | **Use: Tracer Chemical in Oil and Gas Wells** | | |
| **Sites** | **124** | | |
| **Media** | **Dermal** | | |
| Descriptor A | High End | | |
| Quantity A (kg/site/day) | 1.7E-1 | | |
| Frequency A (day/year) | 250 | | |
| Descriptor B | | | |
| Quantity B (kg/site/day) | | | |
| Frequency B (day/year) | | | |
| From | Equipment and Storage Tank Cleaning | | |
| Workers | 992 | | |
| Exposure Type | Liquid | | |

## VI. Focus Decision and Rationale

**Regulatory Actions**

Regulatory Decision: LVE Grant Decision Date: 04/30/2014
Type of Decision:

Rationale: L-14-0271 was granted. Human health hazard concerns were low-moderate for dermal and inhalation exposures. Potential risks to workers were mitigated by negligible inhalation exposures and appropriate dermal PPE. The engineer recommended amending the MSDS to include U.S. standards and a NIOSH-certified respirator, however due to negligible inhalation exposures the changes were not required. Ecotoxicity hazard concerns were high based on accepted acute test data. Potential risks to the environment were low due to no exceedances of the COC during the release period. This LVE was not bound at 200 kg/yr and was assessed at 10,000 kg/yr. The P2REC was forwarded.

COC: Chronic – 3 ppb, Acute – 15 ppb

Summary of Exposures and Releases

Proc
9 sites, 250 days/yr, 0 workers
Inhalation: Not expected
Dermal: Non-quantifiable

Use
124 sites, 350 days/yr, 992 workers
Inhalation: Negligible (VP < 0.001 torr)
Dermal: 1.7E-1 mg/day[redacted]

Releases to Water: 5.9E-5 kg/site-day over 350 days/yr
Releases to Water: 1.0E-4 kg/site-day over 350 days/yr
Or Landfill
Releases via Incineration: 2.3E-1 kg/site-day over 350 days/yr

Fate Releases to Water (50% Removal)
SWC: 6.44E-03 ppb
DW: LADD: 9.44E-09 mg/kg/day, ADR: 3.14E-07 mg/kg/day

P2 Rec Comments:

**Testing:**

**Final Recommended:**

Health:
Eco:
Fate:
Other:

# SAT Report

PMN Number: **L-14-0271**
SAT Date: **4/18/2014**
Print Date: **12/4/2015**

**Related cases:** [redacted]
Health related cases: [redacted]
Ecotox related cases: [redacted]

**Concern levels:**

| **Type of Concern:** | **Health** | **Eco** | **Comments** |
|---|---|---|---|
| **Level of Concern:** | 1-2 | 3 | |

| **Persistence** | **Bioaccum** | **Toxicity** | **Comments** |
|---|---|---|---|
| 3 | 1 | 1<br>Awaiting Human Health Entry<br>Awaiting Human Health Entry<br>Awaiting Human Health Entry | |

**Exposure Based Review:**
**Health:** No
**Ecotox:** No

**Routes of exposure:**
**Health:** Dermal Drinking Water Inhalation
**Ecotox:** All releases to water
**Fate:** ;

**Keywords:**
**Keywords:**

**Summary of Assessment:**

**Fate:**
**Fate Summary:** L-14-0271
FATE: [redacted]
Liquid with MP < 25 C (E)
S = 39 mg/L at 25 °C (E)

VP < 1.0E-6 torr at 25 C (E)
BP > 400 C (E)
H < 1.00E-8 (E)
POTW removal (%) = 0-25 via sorption and biodeg; OECD 306(Closed Btl, Seawater): 0%/28d.
Time for complete ultimate aerobic biodeg ≥ mo
Sorption to soils/sediments = moderate
PBT Potential: P3B1
*CEB FATE: Migration to ground water = moderate

**Health:**

**Health Summary:** Poor absorption all routes based on physical/chemical properties. There are uncertain concerns for solvent irritation to the eye, lung, and mucous membranes.

**Ecotox:**

| Test Organism | Test Type | Test End Point | Predicted | Measured | Comments |
|---|---|---|---|---|---|
| **fish** | **96-h** | **LC50** | 21.7 | | |
| **daphnid** | **48-h** | **LC50** | 14.2 | 1.6 | |
| **green algal** | **96-h** | **EC50** | 19.1 | 0.06 | |
| **fish** | **_** | **chronic value** | 2.5 | | |
| **daphnid** | **_** | **chronic value** | 2.1 | | |
| **algal** | **_** | **chronic value** | 6.9 | 0.032 | |
| **Sewage Sludge** | **3-h** | **EC50** | **_** | | |
| **Sewage Sludge** | **_** | **Chronic Value** | **_** | | |

**Ecotox Values Comments:** Predictions are based on SARs for neutral organics; SAR chemical class = neutral organics; [redacted] log Kow = 3.2 (EPI; [redacted]; liquid with unknown mp (P); S = 32 mg/L at 20 C, pH 7 (P); pH7; effective concentrations based on 100% active ingredients and nominal concentrations; DW hardness <150.0 mg/L as CaCO3; and DW TOC <2.0 mg/L;

Ecotoxicity Test Data Results for L-14-0271: [redacted].

Data submitted with L-14-0271 [redacted] Trade Name: RGTO-015) were for saltwater

species that included the marine invertebrates Acartia tonsa and Mysidia bahia, the sediment dwelling invertebrate Corophium volutater, the marine diatom Skeletonema costatum, and the marine fish Menidia beryllina (Inland silverside). The PMN substance was classified as a Neutral Organics with a moderate predicted water solubility (39 mg/L). Predictions for fate and effects were carried out with a representative structure that contained [redacted]. The molecular weight was [redacted].

Fish Ecotoxicity Test:
Environmental Enterprises USA, Inc. conducted a 7-day toxicity study in the inland silverside (Menidia beryllina) with L-14-0271 (purity not specified) under static-renewal conditions with daily renewal. This study was reported to follow the requirements of EPA-821-R-02-014: "Short Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Marine and Estuarine Organisms" with strict adherence to the requirements of Method 1006. Five replicates of eight M. beryllina were exposed to a dilution water control (synthetic seawater) or the test substance as water accommodated fractions (WAFs) at nominal concentrations of 0.1, 0.5, 2.5, 12.5 and 62.6 parts per trillion (ppt). A 500,000 ppb WAF stock solution was prepared by adding 0.5 g of test substance to 1000 mL of diluent in a 1-L aspirator bottle. The WAF was then mixed for 24 hours on a magnetic stirrer using ½" diameter by 3" long stir bars. The depth of the vortex of each was adjusted to approximately 1/3 the total depth of the solution. After mixing for 24 hours, the WAF was allowed to settle for 60 minutes. After settling, the WAF was collected from the tubular outlet of the aspirator bottle. A second stock solution (5,000,000 ppt) was prepared and used to make a third stock solution at 5,000 ppt. This third stock solution was used to prepare the initial and subsequent renewal test solutions. During the study, temperature was maintained at 25 ± 1°C. The salinity of the dilution water (synthetic seawater) was 25 parts per thousand. There were no significant effects on survival or growth. Based on nominal concentrations, the 7-day NOEC and LOEC values were 62.6 and > 62.6 ppt, respectively, for both survival and growth. This study was considered unacceptable to characterize the chronic fish endpoint since the highest test concentration was greatly below the limit of solubility and 10 mg/L and did not result in an effects determination. In addition the duration was too short.
7-day NOEC (survival and growth) = 62.6 ppt (0.0000626 mg/L)
7-day LOEC (survival and growth) > 62.6 ppt (0.0000626 mg/L)

Invertebrate Ecotoxicity Test:
(1) Opus Plus Limited conducted a 10-day sediment bioassay in marine amphipods (Corophium volutator) with L-14-0271 (purity not specified). Test methods were conducted in accordance with SOP 102, which conforms to the Paris Commission guidelines for conducting sediment toxicity tests with the amphipod Corophium volutator (OSPARCOM 2006). Three replicates of twenty C. volutator were exposed to the test substance at nominal wet weight concentrations of 10, 100, 320, 1000 and 10000 mg/kg. Corresponding nominal dry weight concentrations of 16.34, 161.13, 509.84, 1573.66 and 14690.82 mg/kg were calculated using a wet-to-dry sediment ratio of 1.62. Additionally, five control replicates were tested concurrently in amended sediment combined with filtered seawater. The test substance was considered to be poorly soluble in a preliminary test and was therefore added to the test system via dried sediment. Tests were conducted in 1 L capacity glass beakers each containing 2 cm depth (approximately 150 mL) of amended sediment and 850 mL of overlying seawater (1 ìm filtered ultra violet treated seawater). To prepare the test medium, an appropriate amount of test substance was initially mixed with a

small quantity of dry sediment. The dried sediment and mixed test material was then incorporated with the wet sediment within the mixing container. The mixing vessels were then placed on a platform shaker at approximately150 rpm for 3 hours. After this period, the contents of each container were equally distributed between the replicate vessels. Vessels were covered with a sheet of Perspex perforated with a small hole above the center of each beaker. Aeration was provided and a stream of air bubbles was released at a depth of approximately 6 cm. Over the course of the study, temperature ranged from 14.4-15.5°C, pH ranged from 7.78-8.21, dissolved oxygen ranged from 79-96% and salinity ranged from 35-40 ppt. Mean percent mortality at 0 (control), 16.34, 161.13, 509.84, 1573.66 and 14690.82 mg/kg was 2%, 6.7%, 3.3%, 100%, 100% and 100%, respectively. Based on nominal concentrations, the 10-day LC50 was 330 mg/kg (dry weight). The NOEC and LOEC values were 161 and 510 mg/kg (dry weight), respectively. The 10-day ChV was 286.5 mg/kg (dry weight). Although the approach is reasonable, the organic carbon content of the sediment was not clearly provided and since organic carbon content of sediment may impact the results of the study, there are uncertainties with the results. In addition, a table of the results should have been provided.

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10-day NOEC = 161 mg/kg (dry weight)
10-day LOEC = 510 mg/kg (dry weight)
10-day ChV = 286.5 mg/kg (dry weight)

(2) Opus Plus Limited conducted a 48-hour toxicity study in marine copepods (Acartia tonsa) with L-14-0271 (purity not specified). This study was reported to follow ISO guideline No. 14669 (1999), Water Quality – Determination of acute lethal toxicity to marine copepods and ISO guideline No. 5667-16 (1998), Water Quality Sampling – Guidance on biotesting of samples. The test substance was considered to be poorly soluble in a preliminary test; therefore, exposures were carried out with water accommodated fractions (WAFs). Following a range-finding study, two replicates of ten A. tonsa were exposed to test substance WAFs at nominal concentrations of 0.1, 0.32, 1.0, 3.2 and 10.0 mg/L. Additionally, four replicates of ten A. tonsa were exposed to a dilution water control (treated seawater). WAFs were prepared by the direct addition of the required amount of test substance to seawater followed by gentle stirring for approximately 20 hours and a settling period of approximately one hour. After this settling period, the middle phase of the preparation was siphoned, avoiding incorporation of undissolved particles, if present. During the study, temperature ranged from 19.3-20.9°C and dissolved oxygen ranged from 86-88%. At the start of the study, the pH ranged from 8.09-8.22. The salinity of the dilution water was 36‰. A loading rate of 200 copepods/L was calculated. Mean percent mortality at 0 (control), 0.1, 0.32, 1.0, 3.2 and 10.0 mg/L was 2.5%, 9.6%, 25%, 33.2%, 100% and 100%, respectively. Based on nominal concentrations, the 48-hour LC50 was 1.59 mg/L. Based on the use of WAF methodology and the absence of analytic confirmation of test concentrations, observed adverse effects may have occurred at concentrations of less than the nominal values reported. Other concerns with the study include no reporting of test substance composition in the study report; however, a PMN attachment does provide more polymer weight information for RGTO-015. Considering that the study followed an established guideline and considering that effects were observed at concentrations less than the water solubility limit, the study was considered acceptable.
48-hour LC50 = 1.59 mg/L

(3) Environmental Enterprises USA, Inc. conducted a 7-day survival, growth and fecundity test in mysids (Mysidopsis bahia) with L-14-0271 (purity not specified) under static-renewal conditions with daily renewal. This study was reported to follow the requirements of EPA-821-R-02-014: "Short Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Marine and Estuarine Organisms" with strict adherence to the requirements of Method 1007 and/or the Western Gulf of Mexico OCS General Permit. Eight replicates of five M. bahia were exposed to a dilution water control (synthetic seawater) or the test substance as water accommodated fractions (WAFs) at nominal concentrations of 0.1, 0.5, 2.5, 12.5 and 62.6 parts per trillion (ppt). A 500,000 ppb WAF stock solution was prepared by adding 0.5 g of test substance to 1000 mL of diluent in a 1-L aspirator bottle. The WAF was then mixed for 24 hours on a magnetic stirrer using ½" diameter by 3" long stir bars. The depth of the vortex of each was adjusted to approximately 1/3 the total depth of the solution. After mixing for 24 hours, the WAF was allowed to settle for 60 minutes. After settling, the WAF was collected from the tubular outlet of the aspirator bottle. A second stock solution (5,000,000 ppt) was prepared and used to make a third stock solution at 5,000 ppt. This third stock solution was used to prepare the initial and subsequent renewal test solutions. During the study, temperature was maintained at 26 ± 1°C. The salinity of the dilution water (synthetic seawater) was 25 parts per thousand. A loading rate of 33 M. bahia/L was calculated. There were no significant effects on survival or growth. Based on nominal concentrations, the 7-day NOEC and LOEC values were 62.6 and > 62.6 ppt, respectively, for both survival and growth. This study was considered unacceptable to characterize the chronic invertebrate endpoint since the highest test concentration was greatly below the limit of solubility and 10 mg/L and did not result in an effects determination. In addition the duration was too short.
7-day NOEC (survival and growth) = 62.6 ppt
7-day LOEC (survival and growth) > 62.6 ppt

Algal Ecotoxicity Test:
Opus conducted a 72-hour toxicity study in marine algae (Skeletonema costatum) with L-14-0271 (purity not specified) under static conditions. This study was reported to follow SOP 104, ISO guideline No. 10253 (2006), Water quality – Marine algal growth inhibition test. The test substance was considered to be poorly soluble in a preliminary test; therefore, exposures were carried out with water accommodated fractions (WAFs). Following a range-finding study, three replicates of S. costatum (10,000 cells/mL) were exposed to test substance WAFs at nominal concentrations of 0.1, 0.032, 0.1, 0.32 and 1.0 mg/L. Additionally, six replicates of S. costatum (10,000 cells/mL) were exposed to a dilution control (treated seawater with nutrient medium). The algae were illuminated with a light intensity ranging from 6120-7750 lux with constant shaking. WAFs were prepared by the direct addition of the required amount of test substance to seawater followed by gentle stirring for approximately 20 hours and a settling period of approximately one hour. After this settling period, the middle phase of the preparation was siphoned, avoiding incorporation of undissolved particles, if present. During the study, temperature ranged from 20.7-21.7°C and pH ranged from 8.01-8.67. Salinity of the dilution medium was 36‰. Based on nominal concentrations, the 72-hour EC50 for growth rate was 0.06 mg/L. The 72-hour NOEC and LOEC values were 0.032 and 0.1 mg/L, respectively; since the LOEC is greater than the EC50 a ChV is not calculated. Based on the use of WAF

methodology and the absence of analytic confirmation of test concentrations, observed adverse effects may have occurred at concentrations of less than the nominal values reported. Other concerns with the study include no reporting of test substance composition in the study report; however, a PMN attachment does provide more polymer weight information for RGTO-015. Considering that the study followed an established guideline and considering that effects were observed at concentrations less than the water solubility limit, the study was considered acceptable.
72-hour EC50 = 0.06 mg/L
72-hour NOEC = 0.032 mg/L
72-hour LOEC = 0.1 mg/L

Both acute and chronic duration studies were provided; however, those chronic studies did not test to a high enough concentration to result in an effects determination and did not test to a sufficient duration. Even though concerns with study methodology were reported for the acute studies, submitted acute studies were guideline and suggested hazard in saltwater environments specific for this PMN. Predictive techniques were used to assess chronic hazard levels. An acute CoC of 0.015 mg/L (15 ppb) was calculated from the marine algae 72-hour EC50 of 0.06 mg/L with application of an assessment factor of 4 to account for species sensitivity distributions. A chronic CoC of 3 ppb was calculated from the marine algae NOEC of 0.032 (NOEC used since the LOEC>EC50) and an assessment factor of 10.

Acute CoC: 0.015 mg/L (15 ppb)
Chronic CoC: 0.003 mg/L (3 ppb)

Reviewer: K.Moran

| Factors | Values | Comments |
|---|---|---|
| Assessment Factor | 10 | |
| Concentration of Concern (ppb) Acute | | |
| Concentration of Concern (ppb) Chronic | 3 | |
| SARs | Neutral Organics | |
| SAR Class | Neutral Organics | |
| TSCA New Chemcial Category | Neutral Organics | |

**Ecotox Factors Comments:**

**SAT Chair:** Viktor Morozov
**Fate assessor:** **Ecotox assessor:** **Health assessor:**